REMARKS

A Response to the last Office Action was due by June 22, 2007. A Request for a Two—Month Extension of Time and the associated fee are submitted herewith. Accordingly, this Response is timely filed.

Reconsideration of this application, as amended, is respectfully requested. By this Amendment, claim 1 is being amended to more particularly point out and distinctly claim the subject invention by incorporating the feature of previous 5 therein. Claim 5 has been canceled. Claim 6 is being rewritten in independent form and new claim 17 is being added. The addition of "new matter" has been scrupulously avoided. Claims 1-4 and 6-17 remain in this application.

In the last Office Action, claims 1-12 and 14-16 were examined on the merits while claim 13 was presumable withdrawn from consideration as directed to a non-elected invention.

Claims 1-12 and 14-16 stand rejected under 35 U.S.C. 112, first paragraph as allegedly not satisfying the enablement requirement. This rejection is respectfully, but most strenuously traversed.

An analysis of whether a particular claim is supported by the disclosure in an application requires determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention, without undue experimentation. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the application. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24(CCPA 1970).

In his analysis of the factors to be considered in determining whether the disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, the Examiner describes the nature of the invention as "drawn toward a transdermal device, which under electrostatic properties delivers a biological active substance topically to a subject in need of such therapeutic administration". (Emphasis added)

Further in the Examiner's description of the state of the prior art, the Examiner refers to a teaching of "a modification in transdermal system which alleges to facilitate greater therapeutic activity to specified region". (Emphasis added)

Applicants respectfully submit that there is no requirement for "therapeutic administration" or facilitation of "greater therapeutic activity" in the pending claims. Furthermore, although the disclosure mentions that the dermal patch of the present invention may be used for therapeutic purposes, the primary usage and vast majority of the description is directed to using the patch for screening the sensitization state of a subject with respect to a given allergen. Accordingly, Applicants submit that the Examiner's emphasis on therapeutic administration or enhanced therapeutic activity is misplaced.

The claimed invention is directed to a dermal patch comprising a support having electrostatic properties. A periphery of the support is coated with an adhesive material to create a hermetically closed space between the support and the skin. The support has, in an area not coated with adhesive material, a depression forming a hollow. All or part of a non-adhesive surface of said area of the support is directly covered with at least one biologically active substance in the form of individualized or agglomerated particles. The particles are kept in contact with a non-adhesive surface of the support as the result of electrostatic forces and are released to the skin when the patch is placed on the skin to form the hermetically closed space between the support and the skin. (Claim 1)

The invention thus resides in the development by the inventors of patches that can be made using powdered substances that are maintained on the patch through electrostatic forces. When applied to the skin, the patch allows a release of the substance which can then penetrate the skin. Release of the substance is particularly efficient when a closed space is formed between the skin and the patch, thereby increasing humidity within the space and facilitating release and penetration of the substance.

The specification, as filed, fully discloses how to make the claimed patch and how to use it. Various electrostatic surfaces are discussed (see e.g. page 9, line 29 to page 10, line 38, for example), as well as various formats of the patch (see e.g. pages 11-12, at least). Similarly, methods for forming allergens in the form of individualized or agglomerated particles are described on page 8, line 18 to page 9, line 23, while release of the particles from the patch is fully described on page 11, line 26 to page 13, line 5. Advantages of the patch of the present invention are described, for example, on page 13, lines 17-29; various uses of the patch are described on page 13, line 31 to page 15, line 18. Finally, the specification concludes with two

examples. The second example reports on the results of actual usage of the inventive patch to determine sensitization of children to cow's milk proteins.

Applicants submit that a skilled artisan can reproduce the invention as claimed using the teachings of this application. Furthermore, it is submitted that the criteria set forth in "In re Wands" further confirm the enabling character of the present application.

As described in the background section of the present application, "patch tests" for determining sensitivity to allergens are well known and commonly used. The present invention provides a dermal patch for such use which advantageously employs electrostatic properties. There is nothing uncertain about how to make and use this patch. Those skilled in the art could readily make and use the claimed patch based on the present disclosure and the well developed state of this art.

Concerning the predictability in the art, the Examiner merely raises general assertions with no reference to any particular prior art or citation which would indicate a level of unpredictability in the manufacture or use of dermal patches. In particular, the Examiner contends that the "lack of predictability is high due to various susceptibilities of the subject transdermal system modifications". However, the claims clearly define the patch and the manner according to which all embodiments and components thereof are to be arranged to provide a dermal patch in which the substance is reversibly maintained in contact with the support. Modifications of the patch would still allow efficient contact of the substance with the support through electrostatic forces, and formation of a closed space, do not create unpredictability. The same comment applies to objections raised in connection with the biologically active substance. As stated in the claims, the substance is in the form of "individualized or agglomerated particles" which provides a clear way of carrying out the invention, i.e., allowing contact with the support and release in the closed space. The Examples clearly show an operable embodiment and beneficial use of the invention, and thus fully support the enablement of an electrostatic patch as presently claimed.

Absent citations or prior art which would indicate any unpredictability in the manufacture and use of dermal patches, Applicants believe the non-enablement rejection is inappropriate and should be withdrawn.

Claim 6 has been rewritten in independent form to emphasize the primary usage of the dermal patch to deliver allergens, as fully described in the specification.

The dependent claims, including withdrawn claim 13, are allowable for the same reasons as the independent claims from which they ultimately depend, as well as for their additional limitations.

Since no prior art has been applied against the claims, Applicants believe that this application is in condition for allowance and such action is respectfully requested.

If it would advance the prosecution of this application, the Examiner is invited to contact Applicants' attorney at the below indicated telephone number.

Respectfully submitted,

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